APR - 7 2011

510(k) Summary for Dimension Vista® CDT CAL Dimension Vista® CDT CON L and H

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K110169

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Siemens Healthcare Diagnostics Products GmbH
Emil von Behring Str. 76
Marburg, 35041 Germany

Contact Information:
Siemens Healthcare Diagnostics
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: March 30, 2011

2. Device Name:

Dimension Vista® CDT CAL
Dimension Vista® CDT CON L and H

Classification:

Calibrator, Secondary, Class II
Single-Analyte Controls, Class I

Product Code: JIT; JJX
Panel: Chemistry

3. Identification of the Legally Marketed Device:

Siemens N Latex CDT Test Kit

4. Device Description:

Dimension Vista® CDT CAL
CDT CAL is a liquid human serum based product containing carbohydrate-deficient transferrin.

Dimension Vista® CDT CON L
CDT CON L is a low level, liquid human serum based product containing human carbohydrate-deficient transferrin.

Dimension Vista® CDT CON H

CDT CON H is a high level, liquid human serum based product containing human carbohydrate-deficient transferrin.

5. Device Intended Use:

Dimension Vista® CDT CAL
CDT CAL is an *in vitro* diagnostic product for the calibration of the carbohydrate-deficient transferrin (CDT) method on the Dimension Vista® System.

Dimension Vista® CDT CON L
CDT CON L is an assayed, low level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of carbohydrate-deficient transferrin (CDT).

Dimension Vista® CDT CON H
CDT CON H is an assayed, high level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of carbohydrate-deficient transferrin (CDT).

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista® CDT CAL and CON L and CON H are substantially equivalent to the Siemens N Latex CDT Test Kit (k060677), which contains N CDT Standard, N CDT Control 1 and N CDT Control 2 respectively.

Similarities and Differences

Item	Device (k110169) Dimension Vista® CDT CAL	Predicate N CDT Standard
Contents	4 vials, (4A, 2.0 mL per vial)	3 X 1mL
Storage Temp	2 - 8 °C.	Same
Shelf life	24 months	Same
Composition	CDT CAL is a liquid human serum based product containing carbohydrate-deficient transferrin.	Same

Similarities and Differences

Item	Device (k110169) Dimension Vista® CDT CON L and H	Predicate N CDT Con L and H
Contents	4 vials, (4Low and 4 High, 2.0 mL per vial)	3 X 1mL
Storage Temp	2 - 8 °C.	Same
Shelf life	24 months	Same
Composition	CDT CON L and H are liquid human serum based products containing human carbohydrate-deficient transferrin.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

APR 7 2011

Siemens Healthcare Diagnostics
c/o Kathleen Dray-Lyons
500 GBC Drive
PO Box 6101
Newark, Delaware 19714

Re: k110169
Trade Name: Dimension Vista CDT Calibrator
Dimension Vista CDT Control L, Dimension Vista CDT Control H
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT, JJX
Dated: January 19, 2011
Received: January 20, 2011

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110169

Device Name: **Dimension Vista® CDT CAL**
Dimension Vista® CDT CON L
Dimension Vista® CDT CON H

Indications For Use:

Dimension Vista® CDT CAL
CDT CAL is an *in vitro* diagnostic product for the calibration of the carbohydrate-deficient transferrin (CDT) method on the Dimension Vista® System.

Dimension Vista® CDT CON L
CDT CON L is an assayed, low level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of carbohydrate-deficient transferrin (CDT).

Dimension Vista® CDT CON H
CDT CON H is an assayed, high level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of carbohydrate-deficient transferrin (CDT).

Prescription Use __X__ AND/OR Over-The-Counter-Use____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K110169